DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7118
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JUL 11 2006

WARNING LETTER

Via FED-EX

Refer to MIN 06 - 28

Access Financial Market
7809 Southtown Center, #312
Bloomington, MN 55431

Dear Owner/President:

This letter concerns your firm's marketing of the product Libidus on your website, www.libidus-usa.com. An FDA laboratory analysis conducted by the Food and Drug Administration (FDA) concluded that your product contains acetildenafil, an analogue of sildenafil. Sildenafil is the active pharmaceutical ingredient in Viagra, an FDA-approved drug that is used to treat erectile dysfunction. Statements on your website describe the intended use of Libidus. These statements include, but are not limited to, the following:

Libidus

- "So while erectile dysfunction (ED) drugs like Viagra, Cialis and Levitra treat impotency by redirecting blood flow, **Libidus** goes one step further by also fixing the problem at the libido level."
- "Your penis will become engorged to give better pleasure to your lover"
- "Your erection will be firm, and your penis will be rock hard . . . for as long as you desire"
- "Desensitizes your penis to prevent premature ejaculation"
- "If you choose to ejaculate, you can do so with complete assurance that your penis will never go limp. In fact, your penis will remain just as hard . . . even after ejaculation!"

These statements make clear that Libidus is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (e.g., impotence). Accordingly, Libidus is a drug, as defined by Section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. § 321(g)(1)(B).

Libidus is also a drug under Section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C), because it is intended to affect the structure or function of the human body. Under Section 201(g)(1) (last sentence), the structure/function claims made for a dietary supplement must be made in accordance with Section

403(r)(6) of the Act, 21 U.S.C. § 343(r)(6), or the product is subject to regulation as a drug. Section 403(r)(6) authorizes claims that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body, or characterize the way in which a nutrient or dietary ingredient maintains the structure or function of the body. In the case of Libidus, however, the sexual performance structure/function claims quoted above do not describe the effects of nutrients or dietary ingredients in the product. Rather, these claims are made for the product as a whole and relate to its acetildenafil content. Since acetildenafil is not a nutrient or dietary ingredient but a synthetic analogue of sildenafil, your claims about improvement of sexual function do not conform with 403(r)(6). Accordingly, Libidus is a drug within the meaning of Section 201(g)(1)(C).

Moreover, this product is a new drug, as defined by Section 201(p) of the Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective for its labeled uses.

Under Sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of Libidus without such an approved application violates these provisions of the Act.

Additionally, the product labeling does not declare that your product contains acetildenafil. Further, your website states that Libidus has "...No nasty, unpleasant side effects... Get the Benefits without the Unpleasant effects!" even though acetildenafil likely exhibits similar pharmacological action to sildenafil. This statement falsely asserts that the product does not have the potential to cause side effects. This statement and the failure to disclose the presence of acetildenafil renders your product's labeling false and misleading. Libidus is therefore misbranded under Section 502(a) of the Act, 21 U.S.C. § 352(a).

Furthermore, because your product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use this product safely for its intended uses. Thus, Libidus's labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). Finally, the product is also misbranded under Section 502(f)(2) of the Act, 21 U.S.C. § 352(f)(2), in that its labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with the use of Libidus, particularly since someone who takes Libidus would be unaware of the presence of a sildenafil analogue. For example, patients who take nitrates and consume Libidus are at risk of life-threatening hypotension.

The violations described above are not intended to be an all-inclusive list of your product's deficiencies. It is your responsibility to ensure that the drug products that you manufacture or distribute meet all of the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to enforcement action against you without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and distributors of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution.

You must notify this office in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations and to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Furthermore, please advise this office what actions you will take to address product that you have already distributed.

If your firm does not manufacture the product identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, 212 Third Avenue South, Minneapolis, MN 55401, Attention: Judy E. Heisick, Compliance Officer.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. Any questions regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857.

Sincerely,

W. Charles Becoat

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Director
Minneapolis District

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